

**Public Health Service** 

**Central Region** 

Food and Drug Administration Waterview Corporate Center 10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054

Telephone (973) 526-5006 January 15, 2002

## WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED
Mr. Peter A. La Monica
President
Cape May Foods, Inc.
35 Indian Trail Road
Burleigh, New Jersey 08210

File No.: 02-NWJ-15

Dear Mr. La Monica:

During an inspection of your facility on November 27-29, 2001, our investigator collected samples of your Scungilli Sliced Conch in 6.5 oz. and 29 oz. cans under Collection Report #103516 and #103517, respectively.

Our sample analysis found this product to be misbranded within the meaning of section 403(i)(2) of the Act in that the label fails to declare a sulfiting agent, sodium bisulfite, as an ingredient in the product, which is not exempt from labeling under 21 CFR 101.100(a)(4).

We acknowledge that you have conducted a recall of this product, however you should check the labeling of all raw materials to avoid mislabeling with other products.

In addition, label review of this product revealed that the declared net weight includes the weight of the water and is not the drained weight of the can. The net weight declaration on the can should be listed as drained weight.

As such, the servings per container would depend on the actual drained weight. If the drained weight is less than 110g then the product would meet the definition of a single service container and would have to be labeled accordingly.

The above violations concern labeling requirements and are not meant to be an all-inclusive list of deficiencies on your labels. Label violations can subject the food to legal action. It is your responsibility to assure that your firm and its products are labeled in compliance with all applicable statues enforced by FDA.

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You should notify this office in writing within 15 working days of receipt of this letter outlining the specific steps you have taken to correct the noted violations along with a copy of the revised label. If corrective action cannot be completed within 15 working days, state the reason and the time within which the corrections will be completed.

Please submit your response to the Food and Drug Administration, 10 Waterview Blvd, 3<sup>rd</sup> Floor, Parsippany, New Jersey 07054, Attn: Rosa L. Brown, Compliance Technician.

Sincerely,

Edward-H Welkens, for Douglas I. Ellsworth

District Director

New Jersey District Office